In the United States Court of Federal Claims

OFFICE OF SPECIAL MASTERS

No. 21-0516V

UNPUBLISHED

CATHERINE KANE, Petitioner, v. SECRETARY OF HEALTH AND HUMAN SERVICES, Respondent.	Chief Special Master Corcoran Filed: March 7, 2023 Special Processing Unit (SPU); Findings of Fact; Statutory Six Month Severity Requirement; Influenza (Flu) Vaccine; Shoulder Injury Related to Vaccine Administration (SIRVA)

Diana Lynn Stadelnikas, Maglio Christopher & Toale, PA, Sarasota, FL, for Petitioner.

Christine Mary Becer, U.S. Department of Justice, Washington, DC, for Respondent.

FINDINGS OF FACT[1]

On January 11, 2021, Catherine Kane filed a petition for compensation under the National Vaccine Injury Compensation Program, 42 U.S.C. §300aa-10, *et seq.*[2] (the "Vaccine Act"). Petitioner alleges that she suffered a right shoulder injury related to vaccine administration ("SIRVA"), a defined Table injury or, in the alternative a caused-in-fact injury, after receiving the influenza ("flu") vaccine on October 2, 2020. Petition at 1, ¶¶ 1, 14-15. In particular, she maintains her "vaccine related injuries have lasted more

[1] Because this unpublished Fact Ruling contains a reasoned explanation for the action in this case, I am required to post it on the United States Court of Federal Claims' website in accordance with the E-Government Act of 2002. 44 U.S.C. § 3501 note (2012) (Federal Management and Promotion of Electronic Government Services). **This means the Fact Ruling will be available to anyone with access to the internet.** In accordance with Vaccine Rule 18(b), petitioner has 14 days to identify and move to redact medical or other information, the disclosure of which would constitute an unwarranted invasion of privacy. If, upon review, I agree that the identified material fits within this definition, I will redact such material from public access.

[2] National Childhood Vaccine Injury Act of 1986, Pub. L. No. 99-660, 100 Stat. 3755. Hereinafter, for ease of citation, all section references to the Vaccine Act will be to the pertinent subparagraph of 42 U.S.C. § 300aa (2012).

than six months" (*id.* at ¶ 16), and that she underwent a "surgical intervention with inpatient hospitalization" (Exhibit 5 at ¶ 3 – Petitioner's signed declaration).

For the reasons discussed below, I find the Petitioner continued to suffer the residual effects of her alleged SIRVA for more than six months. *See* Section 11(c)(1)(D)(i) (statutory six-month severity requirement).

I. Relevant Procedural History

Shortly after the case's initiation, Ms. Kane filed her signed declaration,[3] the medical records required under the Vaccine Act, and her PAR Questionnaire. Exhibits 1-11, ECF Nos. 6-7; *see* Section 11(c). On May 7, 2021, the case was activated and assigned to the "Special Processing Unit" (OSM's adjudicatory system for resolution of cases deemed likely to settle). ECF No. 9.

On October 18, 2021, Respondent indicated he had not identified any outstanding medical records or factual issues which could be addressed while awaiting the HHS review. ECF No. 16. During this same time, Petitioner filed updated medical records on several occasions. Exhibit 12-15, ECF Nos. 14, 18-19. Petitioner began finalizing a demand in early 2022. ECF No. 21.

On June 2, 2022, Respondent indicated that he "[wa]s not interested in considering a demand at this time." ECF No. 25. Approximately 45 days later – on July 18, 2022, he filed his Rule 4(c) Report opposing compensation. ECF 26. Specifically, Respondent maintains that Petitioner has not met the Vaccine Act's severity requirement or established onset within 48 hours of vaccination as required for a Table SIRVA injury. *Id.* at 5-6.

II. Issue

At issue is whether Petitioner has satisfied the Vaccine Act's severity requirement. *See* Section 11(c)(1)(D). Because the case did not involve a vaccine related death, Petitioner may satisfy the requirement by establishing that she suffered the residual effects of her alleged SIRVA for more than six months or required a surgical intervention and inpatient hospitalization. *See id.*

[3] Although not notarized, the signed declaration was signed under penalty of perjury as required by 28 U.S.C.A. § 1746. Exhibit 5.

III. Authority

Pursuant to Vaccine Act Section 13(a)(1)(A), a petitioner must prove, by a preponderance of the evidence, the matters required in the petition by Vaccine Act Section 11(c)(1). A special master must consider, but is not bound by, any diagnosis, conclusion, judgment, test result, report, or summary concerning the nature, causation, and aggravation of petitioner's injury or illness that is contained in a medical record. Section 13(b)(1). "Medical records, in general, warrant consideration as trustworthy evidence. The records contain information supplied to or by health professionals to facilitate diagnosis and treatment of medical conditions. With proper treatment hanging in the balance, accuracy has an extra premium. These records are also generally contemporaneous to the medical events." *Cucuras v. Sec'y of Health & Hum. Servs*., 993 F.2d 1525, 1528 (Fed. Cir. 1993).

Accordingly, where medical records are clear, consistent, and complete, they should be afforded substantial weight. *Lowrie v. Sec'y of Health & Hum. Servs*., No. 03-1585V, 2005 WL 6117475, at *20 (Fed. Cl. Spec. Mstr. Dec. 12, 2005). However, this rule does not always apply. "Written records which are, themselves, inconsistent, should be accorded less deference than those which are internally consistent." *Murphy v. Sec'y of Health & Hum. Servs.*, No. 90-882V, 1991 WL 74931, *4 (Fed. Cl. Spec. Mstr. April 25, 1991), quoted with approval in decision denying review, 23 Cl. Ct. 726, 733 (1991), *aff'd per curiam*, 968 F.2d 1226 (Fed.Cir.1992)). And the Federal Circuit recently "reject[ed] as incorrect the presumption that medical records are accurate and complete as to all the patient's physical conditions." *Kirby v. Sec'y of Health & Hum. Servs.*, 997 F.3d 1378, 1383 (Fed. Cir. 2021).

The United States Court of Federal Claims has outlined four possible explanations for inconsistencies between contemporaneously created medical records and later testimony: (1) a person's failure to recount to the medical professional everything that happened during the relevant time period; (2) the medical professional's failure to document everything reported to her or him; (3) a person's faulty recollection of the events when presenting testimony; or (4) a person's purposeful recounting of symptoms that did not exist. *La Londe v. Sec'y of Health & Hum. Servs*., 110 Fed. Cl. 184, 203-04 (2013), *aff'd*, 746 F.3d 1335 (Fed. Cir. 2014).

The Court has also said that medical records may be outweighed by testimony that is given later in time that is "consistent, clear, cogent, and compelling." *Camery v. Sec'y of Health & Hum. Servs*., 42 Fed. Cl. 381, 391 (1998) (citing *Blutstein v. Sec'y of Health & Hum. Servs*., No. 90-2808, 1998 WL 408611, at *5 (Fed. Cl. Spec. Mstr. June 30, 1998). The credibility of the individual offering such fact testimony must also be determined.

Andreu v. Sec'y of Health & Hum. Servs., 569 F.3d 1367, 1379 (Fed. Cir. 2009); *Bradley v. Sec'y of Health & Hum. Servs*., 991 F.2d 1570, 1575 (Fed. Cir. 1993).

A special master may find that the first symptom or manifestation of onset of an injury occurred "within the time period described in the Vaccine Injury Table even though the occurrence of such symptom or manifestation was not recorded or was incorrectly recorded as having occurred outside such period." Section 13(b)(2). "Such a finding may be made only upon demonstration by a preponderance of the evidence that the onset [of the injury] . . . did in fact occur within the time period described in the Vaccine Injury Table." *Id*.

The special master is obligated to fully consider and compare the medical records, testimony, and all other "relevant and reliable evidence contained in the record." *La Londe*, 110 Fed. Cl. at 204 (citing Section 12(d)(3); Vaccine Rule 8); *see also Burns v. Sec'y of Health & Hum. Servs*., 3 F.3d 415, 417 (Fed. Cir. 1993) (holding that it is within the special master's discretion to determine whether to afford greater weight to medical records or to other evidence, such as oral testimony surrounding the events in question that was given at a later date, provided that such determination is rational).

IV. Finding of Fact

I make this severity finding after a complete review of the record to include all medical records, statements, declarations, briefing, and additional evidence filed. Specifically, I base the findings on the following evidence:

- Prior to receiving the flu vaccine on October 2, 2020, Ms. Kane (then 68 years old) suffered from obesity; bipolar disorder; depression; vertigo; varicose veins; lumbar radiculopathy; generalized muscle aches and weaknesses and arthralgias and joint pain; pain in both feet and knees, the lower back, the right hip, and left shoulder; and other common conditions and illnesses. *E.g.,* Exhibit 6 at 5; Exhibit 9 at 31, 42. Although the entries related to prior hip and left shoulder pain did not include an onset date like many other entries, it appears these conditions occurred prior to late 2016. *See* Exhibit 9 at 91 (including the conditions on a December 2016 list of past diagnoses). Less than one year before vaccination, she received a cortisone injection in her left knee. *Id.* at 43.

- On October 2, 2020, Petitioner received the flu vaccine in her right deltoid. Exhibit 1 at 1.

- Nineteen days later, on October 21st, Petitioner visited an urgent care facility, complaining of severe right shoulder pain and stiffness for the last five days. Exhibit 2 at 2. Although she mentioned the flu vaccine she received - mistakenly indicating that it was administered one week ago,[4] Petitioner attributed her right shoulder pain to lifting luggage while recently traveling by plane and train. *Id.* The urgent care physician diagnosed Petitioner as having muscle strain, prescribed pain medication, and instructed her to stretch, to apply ice, and to take Ibuprofen. *Id.* at 3, 5.

- Eight days later, on October 29th, Petitioner was seen by her orthopedist for right shoulder pain currently at a level of three out of ten, but which could increase with movement or at night to nine out of ten. Exhibit 3 at 13-14. Petitioner reported that the pain was not related to any known injury and began while she was on vacation and traveling by train. Upon examination, Petitioner was noted to have limited range of motion ("ROM"), and ex-rays showed a large calcium deposit in her rotator cuff. *Id.* at 14-15. The orthopedist diagnosed Petitioner with calcific tendinitis of the right shoulder, ordered an MRI, and indicated a steroid injection and/or surgery should be considered thereafter. *Id.* at 15.

- When Petitioner returned to the orthopedist on November 10, 2020, she reported that her right shoulder pain had improved slightly since the last visit but was worse than at onset. Exhibit 3 at 8. After reviewing the results of her MRI – showing "a large calcium deposit . . . involving the entire rotator cuff, severe subacromial swelling, [and] no evidence of full thickness tear" (*id.* at 10), the orthopedist recommended surgery to remove the calcium deposit. *Id.* at 9. He ordered a sling and physical therapy ("PT") to begin ten to 14 days post-surgery. *Id.* at 10.

- On November 18, 2020 – 47 days post-vaccination - Petitioner underwent arthroscopic surgery involving rotator cuff repair, subacromial decompression, distal clavicle resection, and extensive debridement including excision of the large calcium deposit. Exhibit 9 at 99. The orthopedic surgeon opined that "the calcium deposit within the rotator cuff tear was likely causing at least some degree [of] chemical irritation . . . [but] there was profound inflammatory reaction within the subacromial space and subacromial bursa likely related to vaccination, hyper inflammation." *Id.* at

[4] This incorrect history would place vaccination as occurring on October 14th, instead of the correct date of October 2nd.

101. In the surgical report, it was noted that the surgery was performed on an outpatient basis. *Id.* at 108.

- At her first post-surgical visit on November 23rd, Petitioner was cleared to begin PT. Exhibit 3 at 5. She attended 19 PT sessions from November 30th through February 22, 2021. Exhibits 4, 12.

- By her second post-surgical orthopedic visit on December 21, 2020, Petitioner reported that she was attending PT twice a week, had no pain currently, and could experience pain as severe as eight of out ten at night. Exhibit 9 at 9. Observing that Petitioner's incisions were healing well, the orthopedist instructed her to transition to over-the-counter pain medication, to continue using her sling and attending PT, and to perform any tolerable activity. *Id.* at 10.

- By her second to last PT session on February 10, 2021, Petitioner reported "feel[ing] stronger and with less discomfort," adding that it "[s]till hurts at night once in while [sic]." Exhibit 12 at 103.

- At her last PT session on February 16th, the therapist assessed Petitioner as making good progress but "still present[ing] with limited ability to lift with resistance above shoulder level." Exhibit 12 at 104. Petitioner was reported to have met all short-term goals and partially met one of three long-term goals. *Id.* at 105.

- At her orthopedic appointment later that same day – February 16th, Petitioner report no current pain but occasional pain as great as seven after PT. Exhibit 13 at 13. It was noted that Petitioner was transitioning to a home exercise program. *Id.* at 15.

- When Petitioner returned to the orthopedist on February 25th, she indicated she "[wa]s doing much better with her ROM and continue[d] to work on her strength." Exhibit 13 at 10. Reporting no current pain (*id.* at 9), she stated she "[wa]s happy with her surgical outcome." *Id.* at 11. Observing that Petitioner continued to experience limited ROM, the orthopedist instructed her to return as needed. *Id.* at 10-11.

- Petitioner did not return to the orthopedist until almost nine months later – on November 9, 2021. At that visit – characterized as a "recheck of right shoulder," Petitioner reported right shoulder pain which began in July 2021, and occurred only when she was playing slot machines. Exhibit 15 at 17.

Upon examination, Petitioner's right shoulder ROM again was noted to be limited. *Id.* at 18. Observing that Petitioner underwent arthroscopic surgery in November 2020, the orthopedist theorized that Petitioner's rotator cuff may need more strengthening through PT or home exercises, or perhaps an injection to shrink any swollen tissue. *Id.* at 17-19. He ordered x-rays and an MRI and instructed Petitioner to follow-up thereafter. *Id.* at 19.

- When Petitioner was seen again by the orthopedist on November 22nd, she again exhibited limited ROM in her right shoulder. Exhibit 15 at 12. The orthopedist informed her that the MRI showed "that her prior rotator cuff repair [wa]s intact but there [wa]s evidence of swelling. *Id.* A cortisone injection was administered. *Id.* It appears this is the last treatment Petitioner received.

Added as an exception to the rule requiring six months of sequelae for vaccine-related injuries not resulting in death in 2000, to allow compensation in intussusception cases which often required surgical intervention but then resolved in less than six months,[5] a petitioner can satisfy the severity requirement by showing that his vaccine-related illness "resulted in inpatient hospitalization and surgical intervention." Section 11(c)(1)(D)(iii). Although Petitioner argues in the alternative that her injury qualifies for this exception (Exhibit 5 at ¶ 3), the medical records establish that her arthroscopic surgery was an outpatient procedure (Exhibit 12 at 108). Thus, she is not excused from demonstrating symptoms of her alleged SIRVA for at least six months - beyond April 2, 2021.

The above medical entries show that Petitioner's alleged SIRVA injury was much improved, but not fully resolved, by early 2021 – almost five months post-vaccination. At orthopedic and PT visits in February, she reported pain only at night or after rigorous activity such as during PT. Exhibit 12 at 103; Exhibit 13 at 9, 13. However, Petitioner continued to exhibit reduced strength and ROM. Exhibit 12 at 104; Exhibit 13 at 10-11. When discharged from PT on February 16th, Petitioner had met all short-term goals, but none of her long-term goals. Exhibit 12 at 105.

Although Petitioner described the right shoulder pain she experienced in July through September 2021, as occurring only when playing slots, this description aligns with the occasional pain she experienced in February 2021, which occurred at night or with movement. And there is no evidence indicating the reduced strength and ROM Petitioner continued to experience through late February 2021 had resolved prior to the

[5] *See Children's Health Act of 2000*, Pub. L. No. 106–310, § 1701, 114 Stat. 1101, 1151 (2000) (codified as amended at 42 U.S.C. § 300aa–11(c)(1)(D)(iii)).

six-month mark – early April 2021. When examined in September 2021, Petitioner exhibited similar, albeit slightly less, limitations in right shoulder ROM. *Compare* Exhibit 13 at 10 *with* Exhibit 15 at 18.

Furthermore, the cause of Petitioner's September 2021 pain, as hypothesized by her orthopedist, was confirmed by MRI to be swelling of the rotator cuff which was repaired in November 2020. Exhibit 15 at 12. This association provides further evidence linking her later pain to the surgery she underwent in November 2020.

Although a close call, I find there is sufficient evidence to link the symptoms Petitioner experienced in July through September 2021, to her November 2020 surgery and alleged SIRVA injury. Additionally, the medical records establish that Petitioner's symptoms had not resolved by late February 2021, almost five months post-vaccination. It is reasonable to infer that her limited ROM continued for more than one month thereafter.

The mildness of Petitioner's post-surgical symptoms, intermittent nature of her pain, and seven-month gap in treatment is highly relevant to damages, and suggests any award in this case for pain and suffering should be modest. But it does *not* mean I cannot find the basic requirement of six months severity met. Accordingly, I find there is preponderant evidence to establish Petitioner suffered the residual effects of her alleged SIRVA for more than six months.

V. Scheduling Order

Despite my finding regarding severity, Petitioner still may not prevail in this case. There are substantial deficiencies which must be countered by Petitioner - related to onset and a viable alternative cause.

At a minimum, these deficiencies would affect the amount of compensation to be awarded. Many SIRVA injuries involve the aggravation of pre-existing, albeit asymptomatic, conditions – a situation meriting a lower award. If successfully litigated, this case falls squarely into that category. And I would caution Petitioner to recognize this fact when finalizing her demand.

In light of my finding regarding the Vaccine Act's severity requirement, Petitioner should forward a reasonable settlement demand and supporting documentation to Respondent. Respondent should consider the demand and determine whether he is interested in engaging in settlement discussions. **The parties shall file a joint status report indicating whether they believe an informal settlement could be reached in**

this case and updating me on their current efforts by no later than Friday, April 28, 2023.

IT IS SO ORDERED.

s/Brian H. Corcoran
Brian H. Corcoran
Chief Special Master